(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 370 785 A1

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 89312112.9

(51) Int. Cl.[5]: A61M 25/00

(22) Date of filing: 22.11.89

(30) Priority: 23.11.88 US 275435

(43) Date of publication of application: 30.05.90 Bulletin 90/22

(84) Designated Contracting States: DE ES FR GB IT

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(54) A catheter having durable and flexible segments.

(57) An epidural catheter is disclosed having a durable (101) and a flexible segment (102) joined together. The flexible segment (102) is inserted into a patient with the use of a well-known needle which is removed by passing the needle over the outside of the catheter. The flexible segment (102) is atraumatic to the surrounding tissue. The flexible segment (102) includes a plastic tube (108) surrounded by a wire coil (109) for pushing the tube into a passageway of the tissue. The distal end of the plastic tube (108) and wire coil (109) are joined to prevent unwinding of the coil when extracted. The tightly coupled wire coil (109) also permits the flexible portion (102) to be easily inserted into the passageway of the tissue. The durable segment (101) joined to the flexible segment (102) includes a stainless steel tube (104) with a flat wire coil (105) surrounding a length of the tube. The stainless steel tube (104) permits fluid at an elevated pressure to pass through the hollow passageway therein without rupturing. The flat wire coil (105) prevents kinking of the semi-rigid stainless steel tube (104). When a fluid at an elevated pressure is received, the distal end of the flexible tube is closed to diffuse the fluid passing through the length of the catheter. Slits (110) are provided laterally on the side of the plastic tube (108) for emitting and diffusing the fluid through the wire coil (109).

A CATHETER HAVING DURABLE AND FLEXIBLE SEGMENTS

This invention relates to catheters and, in particular, catheters having at least two segments.

Catheters of various types and sizes have been used by physicians extensively. One use of the catheter is in providing regional anesthesia which produces profound analgesia with minimal physiologic alterations. When used at the start of an operation, regional anesthesia minimizes the total dosage of inhalation or intravenous anesthetic drugs required, hastens awakening, and permits early ambulation. When administered at the conclusion of surgery, regional anesthesia produces postoperative analgesia with reduced risk of respiratory depression. Furthermore, certain types of pain are difficult to treat with systemic narcotics. For example, a bladder spasm following genitourinary surgery may be exacerbated by systemic opioids but is easily treated with a caudal epidural block. When prolonged analgesia is required, a catheter is inserted into the caudal or lumbar epidural space to provide intermittent or continuous injections of local anesthetics.

Caudal epidural anesthesia is notable for its simplicity, safety, and effectiveness and is one of the most frequently used regional anesthetic techniques for operations below the diaphragm in children.

When continuous pain relief is desired, the only equipment presently available is either a 19 or 20 gauge epidural catheter which is passed through either a 17 gauge Tuohy or an 18 gauge Crawford needle. Designed specifically for adults, these needles are approximately $3\frac{1}{2}''$ long and have an outside diameter ranging from 0.050″ to 0.059″ along with an inside diameter ranging from 0.033″ to 0.041″. However, these needles are extraordinarily cumbersome to use in children, since the distance from the skin to the epidural space is only 10-15mm. Obviously, smaller needles and catheters are desirable.

Continuous lumbar epidural anesthesia is a well-established and accepted technique in adult patients. It differs from caudal epidural anesthesia by the location where the needle is inserted. A lumbar approach has several advantages over the caudal epidural technique. However, the lumbar approach has more problems as well. First, placement of a lumbar epidural needle is technically more difficult than placing a needle into the caudal epidural space, particularly with the 17 and 18 gauge equipment presently available for use. Second, there is a greater risk of unintentionally puncturing the dura. This is commonly known as an unintentional spinal tap with the possibility of severe headaches depending on the size of the dural puncture hole. The smaller the hole, the less likely a headache. Obviously, a 17 or 18 gauge hole in the dura is much more likely to cause a severe headache than a 22 or 23 gauge puncture hole.

The smallest presently offered epidural catheter is a 20 gauge continuous epidural catheter with an outside diameter of approximately 0.035″. This catheter is constructed of a spring wire guide coated with a plastic material. The distal end of the spring wire guide appears to have been stretched to allow the plastic material to form in between the stretched windings. This catheter is advertised as kink-resistant, but is still kinkable particularly when a patient would bend or collapse the catheter by laying on or twisting the body of the catheter outside the insertion site.

Since the plastic material is coated over the spring wire guide, the coating appears to have fluid pressure limitations as well as being susceptible to being easily ruptured.

Another problem associated with the distal end of the catheter is that of tissue ingrowth. Here, tissue is allowed to grow within or between the winding coils of the distal tip. The elastic distal spring tip is also susceptible to uncoiling when the catheter is removed from the patient. This causes trauma to the insertion site as well as possible injury to the dura.

It is clearly desirable to reduce the outside diameter of a catheter to as small a value as is practical. Merely reducing the dimensions of existing catheters, however, introduces very significant problems, one of them being that one must maintain a minimum fluid volume delivery rate.

Delivering a minimum level of fluid volume at an acceptable flow rate and pressure with a small diameter catheter is limited by the inside diameter of the catheter, the thickness of the catheter wall, and the pressure at which the fluid is delivered to the catheter. Calculating the fluid volume at a prescribed flow rate and pressure for a given inside diameter of a catheter is a straightforward matter. However, simply reducing the outside diameter of the catheter, while maintaining the inside diameter, decreases the thickness of the catheter wall and introduces a number of other concerns. These concerns include the susceptibility of the catheter to kinking when bent and the maximum pressure at which the fluid may be delivered without rupturing the catheter wall. As the thickness of the catheter wall decreases, susceptibility of the catheter to kinking increases. At a minimum, kinking of the catheter reduces the fluid volume delivery rate and, in many cases, causes a rupture in the catheter wall with an accompanying loss of fluid. Further-

more, the reduced wall thickness must be capable of withstanding the delivery pressure without a rupture of the wall.

Minimum fluid volume delivery rates may be maintained with an increased delivery pressure when the inside and outside diameters of the catheter are decreased. However, an increase in delivery pressure must not cause injury to the tissue in the vicinity of the catheter. Delivery pressure is also limited by the connector attached at the proximal end of the catheter.

According to the present invention there is provided a catheter as defined in claim 1. The foregoing problems are solved and a technical advance is achieved in an illustrative catheter having both a durable segment for withstanding abusive environments external to the patient and a flexible segment for atraumatic insertion and extraction from patient tissue. The durable segment comprises, for example, a stainless steel metal tube having a hollow passageway for transporting fluids between the distal and proximal ends. The stainless steel metal tube advantageously permits the transportation of fluids entering at pressures in excess of 2,000 psi. This represents a significant advantage over the plastic coated spring wire guide catheter in which fluid pressures are limited without rupturing the plastic coating. The flexible segment is atraumatic to tissue and is pushable through a passageway in tissue for transporting fluid from the durable segment to the tissue. The flexible segment illustratively comprises a plastic tube such as polyimide, which is joined with the durable segment. The flexible segment also includes a helical wire coil preferably surrounding the plastic tube for pushing the flexible segment through a passageway in selected tissue. The wire coil and plastic tube are joined together preferably at or near the distal ends, for preventing the wire coil from uncoiling when extracted and for pushing the flexible segment into the passageway of the tissue during insertion. The windings of the wire coil are tightly coupled to prevent compression and extension during insertion and extraction, respectively.

In one illustrative embodiment, material is also applied to close the distal end of the flexible segment. Openings are slit or formed in the length of the plastic tube to diffuse the emission of fluid being transported therein. Otherwise, fluid at an elevated pressure would be emitted from the distal end causing possible injury to the surrounding tissue. By emitting the fluid along the length of the plastic tube, fluid is further diffused through the wire coil to the surrounding tissue. Materials such as medical grade epoxy are used to both close the distal end of the plastic tube and form a smooth-surfaced or rounded tip thereat.

In a second embodiment, a smooth-surfaced or rounded tip of stainless steel metal is attached or formed at the distal end of the flexible segment to facilitate insertion of the catheter into a passageway in tissue without causing trauma to the tissue. A medical grade adhesive secures the distal ends of the plastic tube and wire coil together.

In a third embodiment for low or minimal pressure fluids at the tip of the catheter, the distal end of the plastic tube is left open for emitting the fluid. The rounded tip is formed by soldering and forming the distal end windings of the wire coil. A medical grade adhesive secures the formed tip to the distal end of the plastic tube.

To virtually eliminate kinking of the stainless steel tube when bent, a coil of flat wire surrounds the stainless steel tube. Alternatively, a round wire tightly wrapped around the metal tube or a spiral trench formed in the tube also advantageously prevents kinking of the tube.

The durable and flexible segments are joined together such as by inserting the proximal end of the plastic tube over the distal end of the stainless steel tube and using, for example, a medical grade adhesive for bonding the two ends together.

The proximal end of the wire coil surrounding the flexible segment is also advantageously joined to the distal end of the metal tube to further prevent expansion and compression of the wire coil. A material such as solder affixes the flat and round wire coils at the proximal end of the stainless steel tube.

When the two segments are joined, a catheter is formed which is passable through very small apertures having diameters less than 0.035", and preferably less than 0.032". Catheters of the present invention are capable of going through 26 gauge thin-wall needles with inside diameters of only 0.012". Catheters of this small size, which are capable of passing sufficient volumes of fluid, represent a significant departure in the art. The strength of the combination of the helical wire and the plastic tube is a factor helping the above reduction to be achieved.

FIG.1 depicts a catheter including a flexible segment and a durable segment;

FIG.2 depicts a cross-section of the flexible segment and the distal end of the durable segment of FIG.1;

FIG.3 depicts a second embodiment of the durable and flexible segments of FIG.2;

FIG.4 depicts a third embodiment of the durable segment of FIG.2; and

FIG.5 depicts a third embodiment of the flexible segment of FIG.2.

Depicted in FIG.1 is an illustrative epidural catheter 100 having a durable elongated segment 101 and a flexible elongated segment 102 which is passable through an aperture having a diameter

less than 0.035", and preferably less than 0.032". Presently, catheters can be fabricated with outside diameters as small as 0.012" for insertion through a 26-gauge thin-wall Tuohy or Crawford needle. A caudal epidural catheter is inserted at the sacrococcygeal ligament. A lumbar epidural catheter is inserted at another position of the spine such as the posterior superior iliac crest. When the needle is inserted, the epidural catheter is inserted through the hollow passageway of the needle into the tissue. When the catheter is in place, the needle is removed over the entire length of the catheter, and a well-known and commercially available medical grade connector 114, such as a Tuohy-Borst connector, which is available from Cook Inc., is attached to the proximal end 103 of the catheter.

A cross-sectional view of the flexible segment 102 and the distal end of durable segment 101 of the catheter is depicted in FIG. 2. Durable segment 101 of the catheter includes a stainless steel tube 104, commonly known as a cannula. In this preferred illustrative embodiment, the outside diameter of the catheter is nominally 0.020" and passable through an aperture having a diameter no greater than 0.022". The stainless steel cannula is commercially available stainless steel tubing preferably having an outside diameter of 0.014" +/- 0.0005" and more prerably in the range 0.008" to 0.020" and preferably an inside diameter of 0.009" +/- 0.0005", and more preferably in the range 0.004" to 0.012". Stainless steel tubing such as this is available from the K-Tube Corporation. As a consequence of the metal tube, fluids may enter the proximal end of hollow passageway 106 of the durable segment at pressures in excess of 2,000 psi. Commonly available medical grade connectors typically limit the pressure at which the fluid can be applied. This essentially nonkinkable durable segment is placed outside and next to the body of a patient without concern for crushing or rupturing the segment due to bending or the patient laying on the durable segment. In addition, a stainless steel tube offers corrosion resistance to body fluids and other substances externally applied.

Coiled in a spiral configuration surrounding the stainless steel cannula is wire 105. Wire 105 is inserted over or wrapped around cannula 104 to prevent kinking when the stainless steel tube is bent.

In this embodiment, flat wire 105 has a rectangular cross-sectional shape with a 0.008" width and a 0.003" height and is wound into a coil having a 0.020" outside diameter. Such a coil is commercially available from Cook Inc. The wire coil is inserted over the cannula.

Depicted in FIG.3 is a second illustrative embodiment of the flexible segment 102 and the distal end of durable segment 101. In this second illustrative embodiment, wire 105 is round 0.004" diameter wire that is tightly wrapped around cannula 104. Wire 105 is wrapped so that the resultant coil does not slide appreciably when the cannula is bent. Here, cannula 104 has an outside diameter of 0.010" and an inside diameter of 0.007". As a result, the overall combined diameter of durable segment 101 is approximately 0.018". Wire 105 may be wrapped from a single strand of wire or from a tightly coupled wire coil having a 0.015" outside diameter. Such a coil is, again, commercially available from Cook Inc.

A third illustrative embodiment of durable segment 101 is depicted in FIG.4. In this third embodiment, cannula 104 comprises a commercially available stainless steel tube having a 0.020" outside diameter and a 0.010" inside diameter with a spiral trench 401 formed therein. Adjacent windings of the trench are spaced approximately 0.020" apart. The depth of the trench is approximately 0.003" with the opening 402 at the outside surface 403 of the cannula being approximately 0.002". The trench is ovally shaped without any sharp discontinuities, such as corners or grooves, to minimize cracks or tears in the cannula when bent. The spiral trench distributes the forces along the length of the cannula when bent to prevent kinking of the tube. The spiral trench is formed in a stainless steel tube by any one of a number of well-known techniques depending on the exact shape of the trench that is desired. Such an embodiment lends itself to less labour intensive manufacture.

Returning to FIGS.1 and 2, flexible segment 102 comprises a plastic tube 108 surrounded by tightly coupled wire coil 109. Plastic tube 108 preferably has an inside diameter preferably within the range 0.006" to 0.018", such as 0.0142" with an approximate wall thickness of 0.0010". The plastic tube preferably has an outside diameter within the range 0.008" to 0.020", such as 0.0162". In the illustrative embodiment, the plastic tube has an overall length of just over 8cm. The plastic tubing comprises a polyimide tubing such as is available from Micro ML Tubing Sales. This tubing comprises a flexible, non-flammable, radiation resistant, and non-corrosive material. In addition, any apertures or openings such as slit 110 are resistant to tearing.

Wire coil 109 includes 0.002" diameter wire with the windings tightly coupled together with very little, if any, spacing therebetween. The outside diameter of wire coil 109 is nominally 0.020". Such wire coil is commercially available from Cook Inc., as well as other suppliers.

The proximal end of the plastic tube is inserted over approximately 2mm of the distal end of stainless steel tube 104.

Adhesive material 111, such as a medical

grade adhesive, is applied to the proximal end of plastic tube 108 and the distal end of stainless steel tube 104 to more firmly position and join the two ends together. A medical grade adhesive, such as formula FMD-13 from the Loctite Corporation, is just one suitable adhesive material for use with this catheter.

After the plastic tube and cannula are joined, wire coil 109 is positioned over and surrounds the plastic tube and cannula as shown. The proximal end of the wire coil 109 and the distal end of flat wire 105 are attached to stainless steel tube 104 using, for example, a solder material 116 at a distance from adhesive material 111.

Plastic tube 108 further comprises a hollow passageway 112 for transporting fluid from passageway 106 of the durable segment to surrounding tissue when positioned therein. To prevent injury to the dura or other surrounding tissue when fluid at an elevated pressure is received, the distal end of the plastic tube is closed with a medical grade epoxy 107. Dexter Hysol casting compound CH-W795 and hardener HW-796 is a commercially available medical grade epoxy. Closing of the distal end of the plastic tube prevents fluid passing through the hollow passageways of the catheter from being emitted at an elevated pressure level. Slits such as 110 are made on opposite sides of the plastic tube laterally parallel to the longitudinal axis thereof for emitting and diffusing the fluid. The tightly coupled windings of wire coil 109 further diffuse the fluid being emitted from the slits at the distal end of the catheter.

Epoxy material 107 is also used to join wire coil 109 to plastic tube 108. This prevents wire coil 109 from unwinding when extracted from a tissue passageway. The joining of the two distal ends also permits flexible segment 102 to be pushed into the passageway of an inserting needle.

To prevent injury or trauma to surrounding tissue, the distal end of the catheter includes a rounded or smooth-surfaced tip 113 formed or attached to the distal end of the wire coil and/or plastic tube. As shown in FIG.2, tip 113 is formed from the epoxy material 107 closing the end of hollow passageway 112 of the plastic tube. After the distal end of the plastic tube is dipped into the epoxy material, the epoxy material is allowed to dry, and tip 113 is formed into a rounded surface using any one of a number of well-known techniques.

As shown in FIG.3, tip 113 in the second illustrative embodiment comprises a metal material 302 which is formed at the distal end of the flexible segment by, for example, welding a stainless steel material to wire coil 109. The distal ends of wire coil 109 and plastic tube 108 are joined by an adhesive material 301 such as well-known and commercially available superglue.

Depicted in FIG.5 is a third illustrative embodiment of the distal end of flexible segment 102. In this embodiment, the distal end of plastic tube 108 is left open for emitting the fluid when the fluid is received at minimal or low pressure levels that are atraumatic to tissue. Tip 113 is formed by applying a solder material 501 to the distal end windings of wire coil 109 and grinding, buffing, and/or polishing the distal end into a smooth or rounded surface. The distal end of the wire coil is secured to plastic tube 108 with medical grade adhesive 502. Slit 110 is not required in this third embodiment.

As previously described with respect to FIG.1, connector 114 is attached to proximal end 103 of the catheter. This connector is then, in turn, connectable to a number of sources for receiving fluid into the catheter at appropriate pressure levels via standard medical Luer fittings. A solder material 115 is also applied to proximal end 103 of the catheter to fixedly position wire 105 to stainless steel tube 104.

This two segment catheter having both a flexible and a durable segment permits continuous long term application of anesthetics or analgesics. Flexible segment 102 is atraumatic to the surrounding tissue. However, durable segment 101 permits continued abusive use without kinking or rupturing. The stainless steel metal also affords a noncorrosive environment.

It is to be understood that the above-described catheter is merely an illustrative embodiment describing the principles of this invention and that other catheters may be devised by those in the art without departing from the spirit and scope of this invention. In particular, this catheter includes a metal cannula surrounded by a wire for providing extraordinary strength for high pressure fluids without kinking. Other such metals and wraps of other materials may also be used. The flexible segment consisting of a plastic tube may be comprised of other flexible materials having a hollow passageway therethrough. A safety wire may also be attached between the proximal and distal ends of the catheter to guard against unexpected material failure.

Claims

1. A catheter for insertion into biological tissue, said catheter comprising a durable elongated segment (101) connected at its distal end to the proximal end of a flexible elongated segment (102) comprising a helical wire coil (109), characterised in that the flexible segment also comprises a plastic tube (108) adjacent to the helical coil and joined thereto (301), the plastic tube serving to control

flow of fluid along and from (110,503) the flexible segment.

2. A catheter according to claim 1, characterised in that the plastic tube extends substantially along the length of and within the coil and is arranged to closely conform to the helical coil when fluid flows from the durable segment to the flexible segment.

3. A catheter according to claim 2, characterised in that fluid flow from the flexible segment is provided by one or more openings (Fig.5 (503) or (110)) in the plastic tube.

4. A catheter according to claim 2 or 3, characterised in that the connection of the flexible segment to the durable segment provides a segment of intermediate flexibility.

5. A catheter according to claim 4, characterised in that the durable segment has an internal tubular member (104) extending beyond the distal end of the durable segment and within the proximal end of the said coil thereby providing the intermediate segment.

6. A catheter according to any one preceding claim, further characterised by a tip (113) joined approximately at or near the distal end of either the tubular member or the wire coil, whereby the catheter is capable of atraumatic insertion in the tissue.

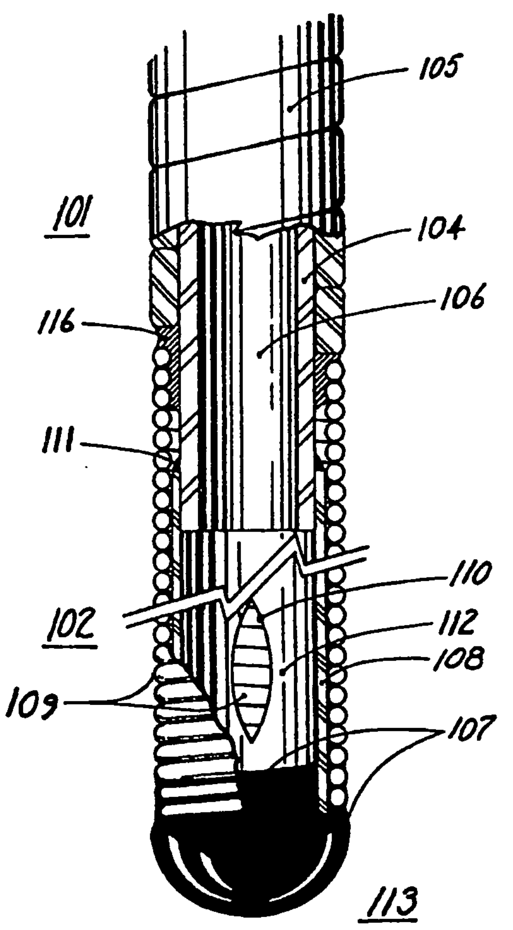
7. A catheter according to claim 6 as appendant to claim 3, characterised in that the opening or openings includes at least one lateral opening (110) capable of dispersing said fluid from within the tubular member through the wire coil to the tissue atraumatically.

8. A catheter according to any one preceding claim, characterised in that the segments are all of constant outer diameter, and in that said outer diameter is less than 0.032″.

9. A catheter according to claim 2 or any claim appendant thereto, characterised in that the plastic tube and the coil are joined approximately at or near the distal ends thereof.

10. A catheter according to claim 2 or any claim appendant thereto, wherein the outer diameter of the catheter is within the range 0.012″ to 0.032″ and the cross sectional diameter of the wire is within the range 0.002″ to 0.006″.

11. A catheter according to claim 10, wherein the plastic tube has an outside diameter within the 0.008″ to 0.02″ and an inside diameter within the range 0.006″ to 0.018″.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113

Fig. 2

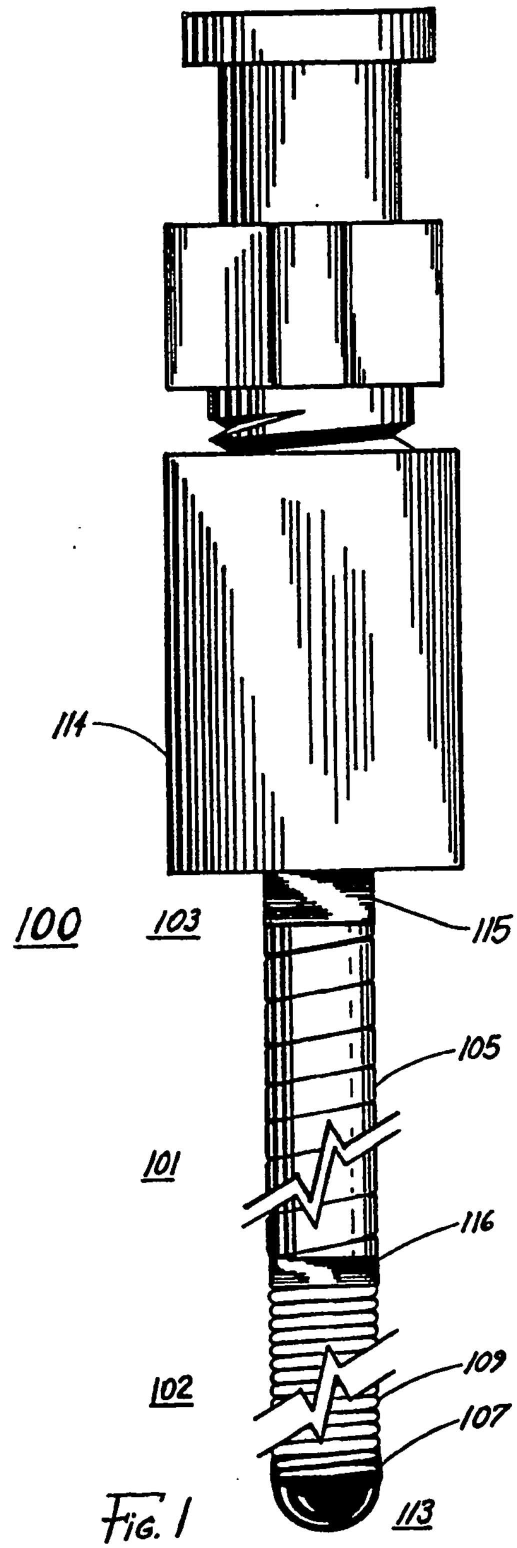
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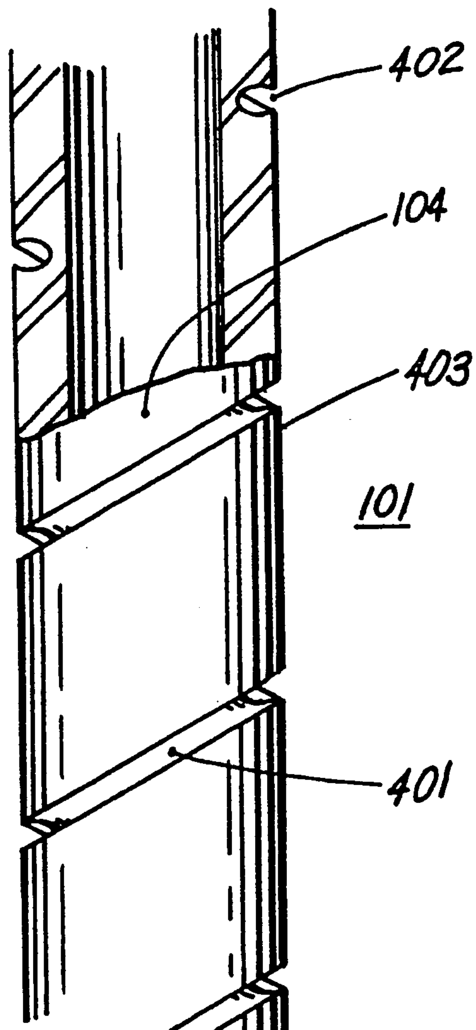
Fig. 1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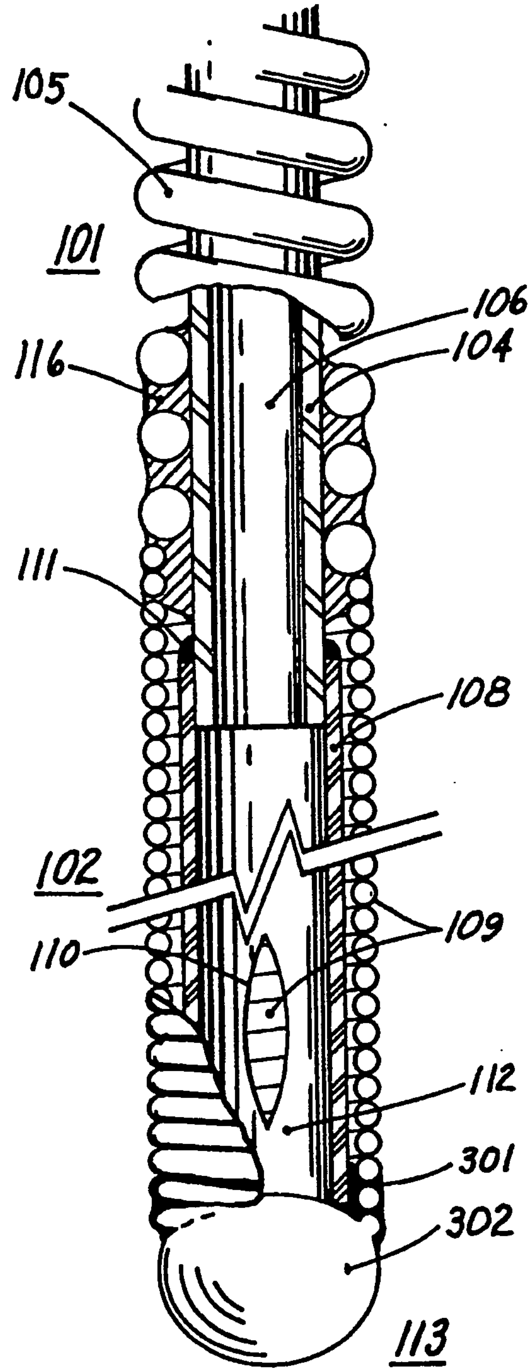
401

Fig. 4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302
113

Fig. 3

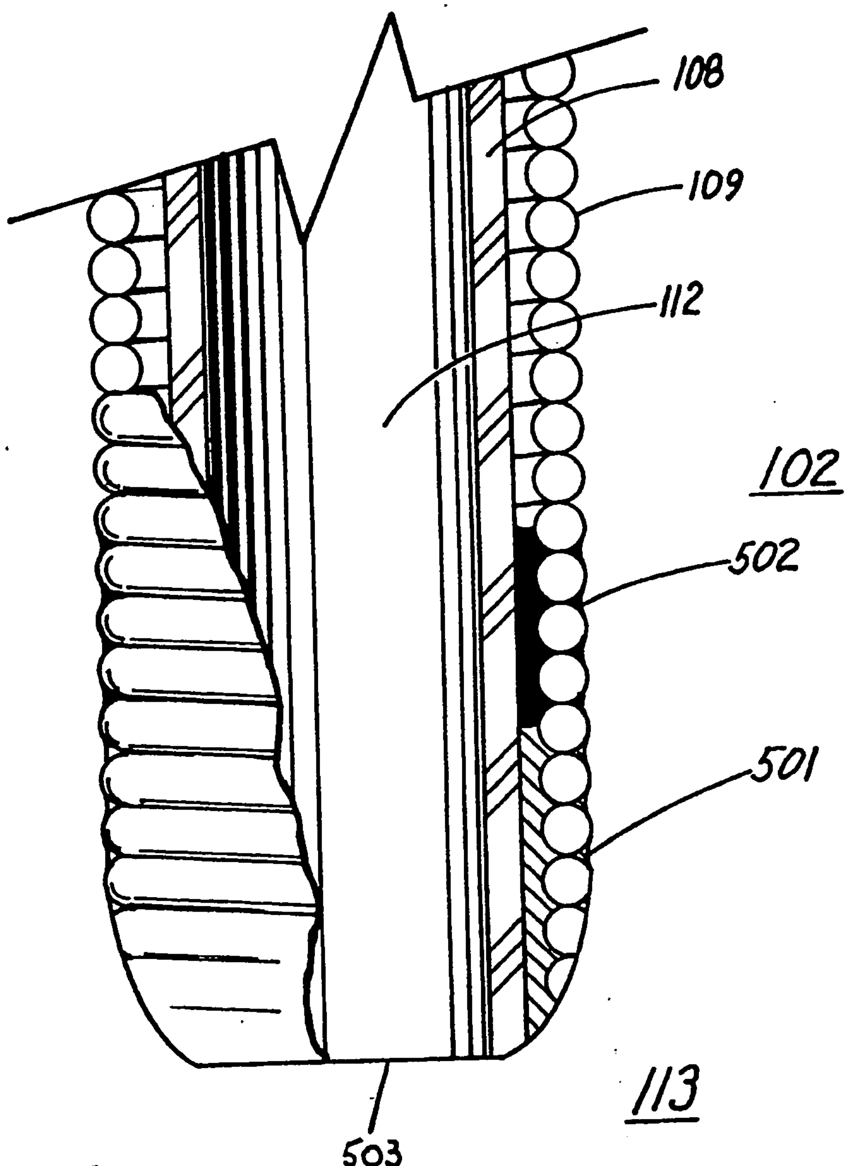

Fig. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 31 2112

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	US-A-4 639 252 (KELLY et al.) * Abstract; column 4, lines 12-32; column 6, line 48 - column 7, line 24; figure 1 * ---	1	A 61 M 25/00
A	DE-C-3 447 642 (CRAMER) * Abstract; column 6, line 55 - column 7, line 21; figure 3 * ---	1	
A	FR-A- 478 285 (SCEMAMA) * Page 2, lines 18-37; figure 2 * ---	1	
A	US-A-3 470 876 (BARCHILON) * @Column 1, lines 20-66; figure 1 * ---	1	
A	EP-A-0 259 945 (C.R. BARD, INC.) * Abstract; figure 3 * -----	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	21-02-1990	ZEINSTRA H.S.J.H.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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